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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------|
| 10/001,949 | 11/13/2001 | Ronald H. Selvester | PAN 311 | 8857 |
| 23581 | 7590 | 12/08/2003 | | |
| KOLISCH HARTWELL, P.C. 520 S.W. YAMHILL STREET SUITE 200 PORTLAND, OR 97204 | | | | |
| | | | EXAMINER SCHAETZLE, KENNEDY | |
| | | | ART UNIT 3762 | PAPER NUMBER |

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,949

Applicant(s)

SELVESTER ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: on page 2, line 13, the term "R/3" appears to be a typographical error.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 and 2 are directed to functional descriptive material and lack the necessary computer-readable medium required to realize the computer program's functionality. The computer program itself is not a process but merely a set of instructions capable of being executed by a computer (see MPEP 2106 and the text concerning functional descriptive material).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xue et al. (Pat. No. 6,507,753) in view of Wagner et al. (the abstract entitled: "Evaluation of a QRS scoring system for estimating myocardial infarct size. I. Specificity and observer agreement").

Xue et al. disclose a program and method for detecting myocardial infarction that includes collecting a subject's ECG data from several preselected, standard ECG leads (col. 3, lines 52-59), establishes, in relation to selected characteristics of a subject's personal data a set of ECG-data criteria to examine (see the "Summary of the Invention" and specifically col. 2, line 57-col. 3, line 6), examines the criteria set (col. 3, lines 14-26), and generates an output indicative of the detection and characterization of an MI (see col. 3, lines 18-23 and also the text associated with elements 118 and 168 of Figs. 4 and 5). Xue et al., however, do not explicitly discuss utilizing R/Q and R/S voltage-amplitude ratio criteria. Clearly one of ordinary skill in the art reading the Xue et al. disclosure would have recognized that Xue et al. did not intend to limit their invention to ST-segment and T-wave criteria only, but to any portion of the ECG waveform that could aid in improving the accuracy of MI detection. The use of the ST-segment and the T-wave is merely given as an example of the types of criteria that may be useful in gender-based applications, but clearly since Xue et al. intend their invention to detect acute cardiac syndromes that are specific with respect to not only gender and/or age, but height, weight, and/or race, the use of other criteria already known to be useful in detecting and characterizing MI would have been considered suitable to the practice of the invention in these aspects as well. If for example it was detected that healthy black males over 200 lbs normally had an R/Q or R/S amplitude that was lower than those of males of any race under 200 lbs, then one would naturally have to adjust the analysis to avoid false indications of MI based on lower than expected R/Q or R/S amplitudes. Wagner et al. disclose that it is old and well-known to monitor R/Q and R/S amplitudes to estimate the size, presence and location of myocardial infarcts. Given the general teachings of Xue et al. to account for statistically significant differences between baseline categories of patients when attempting to enhance specificity and accuracy of MI detection, and given that Wagner et al. show that the R/Q and R/S parameters can be useful and important in enhancing the detection of MI, those of ordinary skill in the cardiac monitoring arts would have seen the obviousness of including these ratios whenever the situation dictated their use.

Regarding claim 2, the examiner considers it inherent that the R/Q and R/S ratios are associated with the various ECG leads since these leads are used to detect Q, R and S amplitudes in any standard lead configuration.

Like comments to those made above apply to claims 3 and 4.

Conclusion

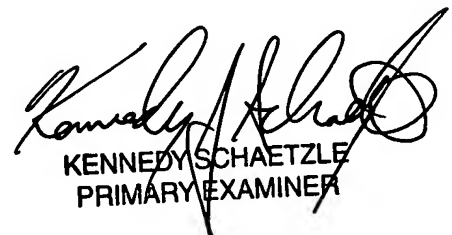
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS
December 3, 2003


KENNEDY SCHAETZLE
PRIMARY EXAMINER